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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,686	07/17/2003	Kenneth K. Sokoll	1038-1266 MIS	9631

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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	PAPER NUMBER
1616	
MAIL DATE	DELIVERY MODE
05/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/620,686	SOKOLL ET AL.	
	Examiner	Art Unit	
	JAMES H. ALSTRUM ACEVEDO	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *71 and 76-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *71 and 76-85* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 71 and 76-85 are pending. Applicants previously cancelled claims 1-70, 72-75, and 86. Applicants have amended claims 80-81. Receipt and consideration of Applicants' arguments/remarks submitted on December 27, 2007 are acknowledged. Applicants are advised that the instant application is under examination by a different Examiner.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 71 and 76-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 71 is internally inconsistent, because said claim indicates on lines 8-9 that the substituent of the polymer structure depicted in said claim as R4 is selected from H1, linear or branched alkyl groups and on line 10 of said claim indicates that R4 is H. It is chemically impossible for R4 to simultaneously be H and a linear or branched alkyl group based upon the structure depicted in claim 71. Appropriate correction is required.

Claims 77, 80, and 84-85 are vague and indefinite, because it is unclear what is a pseudo alpha-amino acid as it refers to an actual molecule. It is noted that the term "pseudo amino acid" is a term of art in computational biology that is used to refer to an abstraction that facilitates modeling and prediction of the structure of proteins (See Shen et al. "PseAAC: A flexible web server for generating various kinds of protein pseudo amino acid composition," *Analytical Biochemistry* **2008**, *373*, p 386-388).

The remaining claims are rejected as depending from a rejected claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 71 and 76-85 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,042,820 (USPN '820). Although the conflicting claims are not identical, they are not patentably distinct

from each other because the cited claims are substantially overlapping in scope and mutually obvious as explained herein. Independent claim 71 of the instant application claims an immunogenic composition comprising particulate polymeric carrier for delivery of an immunogen, wherein the immunogen is chemical attached to the carrier and the carrier has a formula as depicted in instant claim 71 and the carrier has a molecular weight of about 5,000 to about 40,000 daltons. Independent claim 1 of UPSN '820 claims a biodegradable, biocompatible polymer having a molecular weight of about 5,000 to about 40,000 daltons and the same general formula for the carrier claimed in the instant application. The difference between the cited independent claims is that R6 in claim 1 of USPN '820 indicates that this moiety may be selected from H, an amine protecting group, a spacer molecule, or a biologically active species, whereas the same substituent R6 in the instant application is limited to being an immunogen. Because all immunogens are biologically active species the claims of the instant application represent an obvious modification of the cited claims of USPN '820. It is also noted that USPN '820 indicates that the term "biologically active species" includes, such species as macrophage stimulators, which are known immunogens (i.e. anything that induces an immunological response) (col. 4, lines 45-49 and col. 5, lines 53-65). Macrophages are molecules involved in an immunological response. The claims of the cited dependent claims of the instant application and USPN '820 are overlapping in scope and thus mutually obvious. In conclusion, an ordinary skilled artisan at the time of the instant invention would have found claims 71 and 76-85 *prima facie* obvious over claims 1-10 of U.S. Patent No. 6,042,820 (USPN '820).

Claim 71 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 8 of U.S. Patent No. 6,228,423 (USPN '423). Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims are substantially overlapping in scope and mutually obvious as explained herein.

Claim 71 of the instant application has been described above. Independent claim 1 of USPN '423 claims a process of making a polymer having essentially the same formula as the carrier depicted in Applicants' claim 71. The difference between claim 71 of the instant application and claim 1 of USPN '423 is that claim 1 of USPN '423 does not specify that the polymer produced is particulate, has a particular molecular weight, that the R6 substituent is an immunogen, and the fact that the claims of USPN '423 are drawn to a method of making a polymer. Regarding the limitation that the polymer is particulate, dependent claim 8 of USPN '423 recites the step of forming the polymer in microparticles, which reads on the particulate nature of the carrier described in Applicants' claims. Regarding molecular weight of the polymer, this is a result effective parameter that an ordinary skilled artisan would routinely optimize in the preparation of a polymer to tune the macromolecular properties of any polymers obtained by the process of claim 1 of USPN '423. Regarding the fact that the claims of USPN '423 are drawn to a method of making a polymer, it is the Examiner's position that the claimed method of USPN '423 would yield the claimed immunogenic composition of claim 71 of the instant application, because the specification of USPN '423 indicates that the term "biologically active species" (i.e. a possible value for the R6 substituent of the polymer made by the method of USPN '423) includes macrophage stimulators (col. 4, lines 50-54). All immunogens are

biologically active species, thus, claim 71 of the instant application represents an obvious modification of the cited claims of USPN '423. It is also noted that USPN '423 indicates that the term "biologically active species." Macrophages are molecules involved in an immunological response. The claims of the cited dependent claims of the instant application and USPN '820 are overlapping in scope and thus mutually obvious. In conclusion, an ordinary skilled artisan at the time of the instant invention would have found claims 71 *prima facie* obvious over claims 1 and 8 of U.S. Patent No. 6,228,423 (USPN '423).

Conclusion

Claims 71 and 76-85 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-6:30, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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